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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,300	01/23/2004	Zhaolin Wang	364-2US	4632

20212 7590 01/11/2005

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EXAMINER

GRAVINI, STEPHEN MICHAEL

ART UNIT	PAPER NUMBER
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3749

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER
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20040908

DATE MAILED:

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Commissioner for Patents

**Office Action Summary**

Application No.

10/762,300

Applicant(s)

WANG ET AL.

Examiner

Stephen Gravini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) 1-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on December 2003. It is noted, however, that applicant has not filed a certified copy of the priority application as required by 35 U.S.C. 119(b).

#### ***Claim Rejections - 35 USC § 102***

Claims 1-2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by reference C1, cited by the applicants. That reference is considered to disclose the claimed invention comprising:

spraying a carrier liquid containing a powder forming ingredient to form a flow of liquid droplets (please see page 115 right column);

entraining the flow of liquid droplets within a concurrent flow of coolant for sufficient time to freeze the liquid droplets into frozen particles (please see page 115 right column); and

drying the frozen particles to form a dry powder (please see page 116 left column). Reference C1 is also considered to disclose a powder forming ingredient suspended or dissolved in a carrier liquid and a flow of liquid droplets entrained within a concurrent flow of coolant (see page 116 right column) and coolant temperature within a first temperature range during freezing of the liquid particles and a temperature warmer than the first temperature range during drying of the frozen particles (pages 116-117).

Claims 10-14 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Maa et al. (US 6,284,282). Maa is considered to disclose the claimed invention comprising:

providing a flow of liquid droplets containing a powder forming ingredient to form a flow of liquid droplets (please see column 5 lines 5-35);

treating the liquid droplets with a flow of coolant inside the chamber to freeze the liquid droplets to form frozen particles prior to deposition (please see column 16 lines 7-30 and column 14 lines 60-61);

depositing the frozen particles on a collector (please see column 17 line 63 through column 18 line 26 wherein the disclosed plate is considered to anticipate the claimed collector because both collect depositions); and

after deposition of the frozen particles, drying the deposited frozen particles, and to form a dry powder and coolant concurrent with the flow of liquid droplets (please see column 18 lines 29-36). Maa is also considered to disclose flow of coolant for drying frozen particles is in co-direction with the gravity as shown in figure 1, chamber wall adherence prevention and more than one powder forming ingredient (column 27 lines 6-22), and the flow of gas formed by the vaporization of cold liquid nitrogen (column 16 lines 7-30).

Claims 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Soltani Ahmedi et al. (US 5,900,384). Soltani is considered to disclose the claimed invention comprising:

a chamber 7 having an atomizer 17 at one end of the chamber, the atomizer being connected to a source of the ingredient carrier liquid 9 (wherein the disclosed supply line is considered to anticipate the claimed carrier liquid because it carries liquid) to produce a flow of liquid droplets;

an injection system 15 for providing a flow of coolant that entrains liquid droplets sprayed by the atomizer;

a source of coolant 28 for the nozzle system; and  
a collector 23 spaced from the atomizer sufficiently that liquid droplets atomized by the atomizer are frozen by the flow of coolant before contact with the collector. Soltani is also considered to disclose the claimed nozzle system and atomizer are oriented to provide concurrent flows of coolant and liquid droplets as shown in figure 1, a ring nozzle at column 8 line 13 wherein the disclosed spinning disk atomizer is considered to anticipate the claimed ring nozzle because both are circularly oriented, the nozzle system is arranged around a porous wall defining a flow chamber through which the flow of liquid droplets passes at column 8 lines 16-30, a collector filter 25 at an exit from the chamber, and the atomizer and collector are at opposed ends of the chamber as shown in figure 1.

### ***Claim Rejections - 35 USC § 103***

Claims 4-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over reference C1 in view of Soltani. Reference C1 is considered to disclose the claimed invention, as discussed above under the anticipatory rejection, except for the claimed nozzle, chamber, filter collection, and more than one powder feature. Soltani is

considered to disclose a nozzle, chamber, filter collection, and more than one powder feature at column 8 lines 1-54. It would have been obvious to one skilled in the art to combine the teachings of reference C1 with the teachings of a nozzle, chamber, filter collection, and more than one powder feature, considered disclosed by Soltani for the purpose of processing frozen particles subject to a lyophilization process.

Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over reference C1 in view of Maa. Reference C1 is considered to disclose the claimed invention, as discussed above under the anticipatory rejection, except for the claimed gas formed by the vaporization of cold liquid nitrogen, porous side walls, and a filter. Maa, another method of creating powder, is considered to disclose gas formed by the vaporization of cold liquid nitrogen at column 8 lines 1-54, porous side walls as shown in figure 1, and a filter at column 15 line 54 through column 16 line 6. It would have been obvious to one skilled in the art to combine the teachings of reference C1 with the teachings of gas formed by the vaporization of cold liquid nitrogen, porous side walls, and a filter, considered disclosed by Maa for the purpose of processing frozen particles subject to a lyophilization process.

### ***Response to Arguments***

Applicant's arguments filed December 12, 2004 have been fully considered but they are not persuasive.

As a preliminary matter, applicant argues that examiner agreed that incorporation of claim 3 into claim 1, would overcome the rejection. In both interviews, it was agreed

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that the rejection would be overcome by patentably distinguishing the invention over the prior art and not agreed that the claimed entraining, treating/depositing/drying, and nozzle atomizer are disclosed in the prior art. In other words, examiner considers those features disclosed in the prior art, but applicants do not agree with examiner's opinion.

*anticipation*

Applicants argue that the claimed entraining a flow of liquid droplets within a concurrent flow is not disclosed in primary reference C1 with respect to claims 1-2 and 8. However in the first full paragraph of page 115, right column, the disclosed compound injectable examples when read in conjunction with freeze-drying and spray-drying inherently anticipates the argued feature because injecting a compound will entrain liquid droplets (including an injectable compound) when either spraying or freeze drying in flow treatment of a substance. The rejection is considered appropriate and therefore maintained.

The amendment of claim 10 necessitated a new search and/or consideration so the argument with respect to claims 10-14 is moot based on the new ground of rejection.

Applicants argue that claims 15-20 overcome primary reference Soltani because the function is different than the claimed invention. It is considered that the structure of Soltani anticipates the claimed structure and that the first line of column 8 of that reference allows for cooling, as claimed. The claimed frozen liquid droplets are considered to be disclosed in the first full paragraph of column 8, since the disclosed ice



bath and cold trap inherently anticipated the argued, but not claimed in the body of the independent claim, spray freeze drying. The rejection is considered appropriate and therefore maintained.

*obviousness*

Applicants argue that since the anticipatory rejections should be withdrawn, the obviousness rejections should also be withdrawn. Since examiner considered the anticipatory rejections to be appropriate, the obviousness rejections are also considered appropriate and therefore maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gravini whose telephone number is 571 272

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4875. The examiner can normally be reached on normal weekday business hours (east coast time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ira S. Lazarus can be reached on 571 272 4877. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMG  
January 7, 2005

*Stephen M. Shamir*